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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,783	09/28/2001	Stanko Bodnar	CRD-0967	5435

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EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,783	BODNAR ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This final action is in response to the amendment received on 03/30/2006

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-10, 20, 21 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muth et al (U.S.P.N. 5,472,702) in view of McGowan, Jr. (U.S.P.N. 5,749,203) and Mitchell (EP 0 568 310) as further evidenced by Sigma-Aldrich (biocompare.com Internet printout).

With respect to claims 1 and 20, the Muth reference teaches the following: positioning packaged (col.1, lines 19-24, col.2, lines 24-26 and col.5, lines 5-9), drug coated medical device such that the drug contains an anti-proliferative agent (col.4, lines 40-42 and the specification on page 15 teaches that an example of anti-proliferative agents are antibiotics) in a sterilization chamber (col.7, line 38), increasing and maintaining the temperature in the sterilization chamber in the range from 25-35 degrees Celsius and the relative humidity in the range from 40%-85% for a predetermined time period (col.6, lines 43-46), injecting a sterilization agent at a predetermined concentration into the chamber and maintaining the temperature in the range from 25-35 degrees Celsius and the relative humidity in the range from 40%-85% for a predetermined time period (col.7, table, lines 54-59) and removing the sterilization agent from the chamber through a plurality of vacuum washes over another predetermined time period by maintaining the chamber at a temperature in the range of 30-40 degree Celsius (col.7, table, Exhaust, lines 66-67 and col.8, lines 1-2). With respect to claims 1 and 20, the Muth reference fails to teach the following: applying another preconditioning step, creating a vacuum, using nitrogen washes steps and the use of rapamycin. The McGowan reference teaches that preconditioning medical articles is known in the art of ethylene sterilization (col.1, lines 26-27 and lines 36-44).

The McGowan reference further teaches that creating a vacuum (col.1, lines 52-64) and applying nitrogen rinses (col.2, lines 12-14) are also conventional steps in such an art. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Muth reference to include an additional preconditioning step since at elevated temperatures ethylene oxide gas is thought to be more molecularly active and therefore performs more effectively as a sterilizing agent as taught by the McGowan reference (col.1, lines 36-40).

As to the limitation that the drug coated on the medical device comprises a compound that inhibits MROR and binds FKBP12 in claims 1-20, Muth discloses a method of sterilizing drug coated medical devices; however, it is unclear whether the drugs in Muth include a compound that inhibits MTOR and binds FKBP12. The Mitchell reference, which is in the art of dispensing therapeutic compounds impregnated on a vascular stent (page 3, numbered lines 20-21 and numbered lines 35-37), teaches it is known in the art to provide drug coated medical devices with a compound such as rapamycin in order to treat patients with vascular disease. The ability of Rapamycin to inhibit mTOR and to bind to FKBP12 is an inherent property as evidenced by the Sigma-Aldrich Internet printout. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Muth reference by sterilizing a drug coated medical device where the drug includes the compound in order to treat patients with vascular disease and further since rapamycin is known to inhibit transplantation rejection in mammals (page 3, numbered lines 12-13) making organ donations safer for recipients.

With respect to claims 3, 7, 10, 28 and 31, the Muth reference teaches the following: the first predetermined period is three hours (col.6, lines 45-46), removing the sterilant from the packaged drug coated medical device (col.7, table, exhaust) and a biocompatible vehicle or coating that includes an agent in therapeutic dosages (col.8, lines 27-31).

With respect to claims 2, 4-6, 8-9, 21 and 29-30, the McGowan reference teaches the following: reducing the pressure in the chamber to under 10 kPa (col.10, lines 37-45), injecting gaseous ethylene oxide at a concentration from 200-1200 mg/l over a second predetermined period of 6 hours (col.2, lines 5-9), injecting ethylene oxide at a concentration from 800-950 mg/l over a second predetermined period of 6 hours (col.2, lines 5-9), removing the sterilant through a series of alternating vacuum and nitrogen injection stages over a third predetermined period from 2-48 hours (col.2, lines 12-14 and lines 60-65), removing the packaged drug coated medical device from the chamber and positioning it in a controlled environment (col.2, lines 18-22), circulating ambient air (col.2, lines 13-14), maintaining the temperature from 10-70 degrees Celsius (col.2, lines 21-22) over time period from 1hour-2 weeks (col.2, lines 64-65) or over time period from 12 hours-7 days (col.2, lines 64-65) and placing the packaged drug coated medical device in a preconditioning chamber (col.1, line 27) then maintaining the temperature from 10-70 degrees Celsius (col.1, lines 31-32) and the relative humidity from 20%-95% (col.1, lines 32-33) over a time period of 1 hour-5 days (col.1, lines 34-35).

5. Claims 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muth et al (U.S.P.N. 5,472,702) in view of McGowan, Jr. (U.S.P.N. 5,749,203), Mitchell (EP 0 568 310) as further evidenced by Sigma-Aldrich (biocompare.com Internet printout) as applied to claim 21 and further in view of Popescu et al (U.S.P.N. 5,464,580).

With respect to claim 22, the Muth reference, the McGowan reference and the Mitchell reference all fail to disclose a temperature range and a time interval as recited in the claim; however, both the Muth reference and the McGowan reference disclose a relative humidity range value that falls within the recited range, for example, the McGowan reference teaches preconditioning at a relative humidity from 40%-80% (col.1, lines 31-32). The Popescu et al reference, which is in the art of sterilizing medical equipment using ethylene gas, teaches preconditioning at 25 degree Celsius for a time period from 60-90 minutes (col.5, lines 24 and 35-36). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Muth reference by adjusting the temperature range and the exposure time interval since such modifications is a matter of optimization as evidenced by the Popescu reference.

Claims 23-27 have already been addressed above with respect to claims 2-6.

6. Claims 11-13 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muth et al (U.S.P.N. 5,472,702) in view of McGowan, Jr. (U.S.P.N. 5,749,203), Mitchell (EP 0 568 310) as further evidenced by Sigma-Aldrich

(biocompare.com Internet printout) as applied to claims 10 and 20 and further in view of Rich (U.S.P.N. 6,025,414) and Pharriss et al (U.S.P.N. 3,675,647).

With respect to claims 11-12 and 32-33, the Muth reference, the McGowan reference and the Mitchell reference all fail to teach using the polymers poly (ethylene-co-vinyl acetate) and polybutylmethacrylate as coating material; however, the Rich reference, which is in the art of designing polymeric compositions to be used in implants, teaches that poly (ethylene-co-vinyl acetate) is incorporated into layers of implants (col.3, lines 36-37 and col.4, line 10). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify composition of the medical devices coated in the Muth reference to include the polymer poly (ethylene-co-vinyl acetate) as taught by the Rich reference since it is known for it resiliency (col.4, lines 2-3).

With respect to claims 11-12 and 32-33, the Rich reference fails to teach using the polymer polybutylmethacrylate; however, the Pharriss reference, which is in the art of designing implant devices, teaches using polybutylmethacrylate (col.3, line 63). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify composition of the implants in the Rich references to include the polymer polybutylmethacrylate as taught by the Pharriss reference since it is known to be biologically acceptable flexible, resilient, polymeric material (col.3, lines 59-60).

With respect to claims 13 and 34, the Muth reference teaches incorporating the agent into the first layer (col.8, lines 28-30).

7. Claims 14-19 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muth et al (U.S.P.N. 5,472,702) in view of McGowan, Jr. (U.S.P.N. 5,749,203), Mitchell (EP 0 568 310) as further evidenced by Sigma-Aldrich (biocompare.com Internet printout) as applied to claims 10 and 20 and further in view of Gingras (WO 00/38754).

With respect to claims 14-19 and 35-40, the Muth reference, the McGowan reference and the Mitchell reference all fail to teach incorporating polyfluoro copolymers made up of first moiety and second moiety into medicated medical devices; however, the Gingras reference, which is in the art of designing biocompatible stents teaches combining various biocompatible polyfluoro copolymers with polyfluoro monomers (page 10, lines 5-10) in coating layers for stent such that the coating layers are made of first and second moieties that is intrinsically combined in various concentration ranges. Also, the Gingras teaches the use of hexafluoropropylene (page 10, line 10). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify composition of the coatings for medical devices in the Muth reference to include hexafluoropropylene as taught by the Gingras reference since such a compound is known to be biocompatible (page 10, line 5).

Response to Arguments

8. Applicant's arguments filed on 03/30/2006 have been fully considered but they are not persuasive.

On page 12 of the Remarks section, applicant argues that, "However, the Examiner has now cited Mitchell which discloses a composition comprising heparin and

rapamycin. It is respectively submitted that the Examiner is utilizing hindsight along with the claims as a template to pick and choose the references and this is not permitted."

The Mitchell reference, which is in the art of dispensing therapeutic compounds impregnated on a vascular stent (page 3, numbered lines 20-21 and numbered lines 35-37), teaches the use of rapamycin. The ability of Rapamycin to inhibit mTOR and to bind to FKBP12 is an inherent property as evidenced by the Sigma-Aldrich Internet printout. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Muth reference by additionally including rapamycin to the Muth's composition since rapamycin is known to inhibit transplantation rejection in mammals (page 3, numbered lines 12-13) making organ donations safer for recipients.

The various motivation statements supporting obvious prima facie case for addressing instant claims 1-40 with regard to combining Muth McGowan and Mitchell are found in the references them selves as shown above.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Wikipedia. Org Internet printout is further evidence to the inherent property of rapamycin.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monzer R. Chorbaji MRC
06/02/2006

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER